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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,144	06/29/2006	Christopher Bayly	MC100YP	9878
210	7590	09/25/2009	EXAMINER	
MERCK AND CO., INC			CHANDRAKUMAR, NIZAL S	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07065-0907			1625	
			MAIL DATE	DELIVERY MODE
			09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,144	Applicant(s) BAYLY ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10 and 12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 371 of PCT/CA05/00008 01/06/2005.

Claims 1-12 are before the Examiner and subject to the following:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is CR1CR2, Z is CR1R2.

Group 2, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is CR1CR2, Z is O.

Group 3, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is CR1CR2, Z is S or SO2.

Group 4, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is CR1CR2, Z is NR9.

Group 5, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is SO2, Z is CR1R2.

Group 6, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is SO2, Z is O.

Group 7, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is SO2, Z is S or SO2.

Group 8, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is SO2, Z is NR9.

Group 9, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is C=O, Z is CR1R2.

Group 10, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is C=O, Z is O.

Group 11, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is C=O, Z is S or SO2.

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Group 12, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is C=O, Z is NR9.

Group 13, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is NR9, Z is CR1R2.

Group 14, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is NR9, Z is O.

Group 15, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is NR9, Z is S or SO2.

Group 16, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is O, Y is NR9, Z is NR9.

Group 17, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is CR1CR2, Z is CR1R2.

Group 18, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is CR1CR2, Z is O.

Group 19, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is CR1CR2, Z is S or SO2.

Group 20, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is CR1CR2, Z is NR9.

Group 21, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is SO2, Z is CR1R2.

Group 22, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is SO2, Z is O.

Group 23, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is SO2, Z is S or SO2.

Group 24, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is SO2, Z is NR9.

Group 25, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is C=O, Z is CR1R2.

Group 26, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is C=O, Z is O.

Group 27, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is C=O, Z is S or SO2.

Group 28, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is C=O, Z is NR9.

Group 29, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is NR9, Z is CR1R2.

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Group 30, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is NR9, Z is O.

Group 31, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is NR9, Z is S or SO₂.

Group 32, claim(s) 1-8, 11, drawn to compounds of given formula wherein X is NR9, Y is NR9, Z is NR9.

Groups 33-64, claim(s) 9, drawn to process of making compositions comprising compounds of Group 1-32 respectively. Thus, for example, Group 34 corresponds to process of making compositions comprising compounds of Group 2.

The inventions listed as Groups 33-64 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature to all the groups is well-known in the art. For example, the common technical feature, i.e., the invariant structural moiety is found in the teachings of Zhou et al. Bioorganic and Medicinal Chemistry Letters, 13, (2003), 139-141 (applicant provided reference).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

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above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12 provides for the use of compassions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10 and 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/
Examiner, Art Unit 1625